Immuno concepts

K013283

NOV 14 2001

510(k) SUMMARY

Date Prepared: July 23, 2001
Contact Person: Eric S. Hoy, Ph.D., SI(ASCP)
Name of Device:

- Trade Name - RELISA® PR3-ANCA Test System for Antibodies to Proteinase 3
- Common Name - Anti-PR3 Antibody Enzyme Immunoassay Test Kit
- Classification Name - Test System, Antineutrophil Cytoplasmic Antibodies (ANCA) (21 CFR 866.5660)

Legally marketed device with which this device has been shown to be equivalent:

Bindazyme™ Anti-PR3 Enzyme Immunoassay Kit manufactured by The Binding Site, Ltd., Birmingham, England, UK, K981029.

Description:

This is an enzyme immunoassay for the detection of antibodies to Proteinase 3 (PR3) in human serum.

Intended Use:

This is an enzyme immunoassay test system for the detection of antibodies to Proteinase 3 (PR3) in human serum. This test system is to be used as an aid in the detection of antibodies associated with Wegener's granulomatosis and other vasculitides.

Summary of Technological Characteristics Compared to the Predicate Device:

Technologically, this device is similar to the predicate device with the following exceptions:
a) The predicate device has all 96 microwells sealed in a single pouch. The present device has each eight well strip of microwells sealed in an individual pouch, so that unused wells remain in the pouches, and maintain at least 12 months stability.
b) The predicate device uses six calibrator sera, the present device uses five calibrator sera.

Description of Laboratory Data That Indicate Substantial Equivalence:

The Immuno Concepts RELISA® PR3 Test System was compared to the Bindazyme™ Anti-PR3 Enzyme Immunoassay Kit manufactured by The Binding Site, Ltd., Birmingham, England, UK. (K981029). The population studied consisted of 206 samples which were submitted to clinical laboratories for ANCA, MPO and PR3 testing, but without specific diagnoses, 7 samples which were from patients with a diagnosis of Churg-Strauss syndrome, 18 patients with a diagnosis of vasculitis, 25 patients with a diagnosis of Wegener's granulomatosis, 261 samples from male blood donors, and 239 samples from female blood donors. All samples were tested in parallel on the predicate device and the subject device. Based on this comparison, the following data were obtained:

		Bindazyme™ Anti-PR3 Enzyme Immunoassay Kit	
		Positive	Negative
Immuno Concepts RELISA® PR3-ANCA Test System	**Positive**	179	8
	Negative	4	563

These data yield the following statistics: relative sensitivity, 97.8%; relative specificity, 98.6%; and overall agreement, 98.4%

Among the 8 "false positive" samples, 2 showed a P-ANCA pattern by immunofluorescence, 4 showed a C-ANCA pattern by immunofluorescence, and 2 did not demonstrate any immunofluorescent pattern. Two of the samples that showed a C-ANCA pattern by immunoflurescence and a positive RELISA® PR3 were from patients with a diagnosis of Wegener's granulomatosis, and one of the samples that showed a P-ANCA pattern by immunofluorescence and a positive RELISA® PR3 was from a patient with a diagnosis of Churg-Strauss syndrome. These samples may actually represent "false negative" results on the predicate device.

In accordance with 21 CFR 807.92(b)(3), we conclude from these data that the present device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 4 2001

Eric Hoy, Ph.D., SI (ASCP)
Chief Scientific Officer, Regulatory Affairs
Immuno Concepts, Inc.
2280 Springlake Road, Suite 106
Dallas, Texas 75234

Re: K013283
Trade/Device Name: Immuno Concepts RELISA® PR3-ANCA Test System for Antibodies to Proteinase 3
Regulation Number: 21 CFR § 866.5660
Regulation Name: ANCA Test System
Regulatory Class: II
Product Code: MOB
Dated: September 27, 2001
Received: October 2, 2001

Dear Dr. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 4 2001

510(k) number (if known): K013283

Device Name: RELISA® PR3-ANCA Test System for Antibodies to Proteinase 3

Indications for use:

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(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013283

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)